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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/842,833 | 04/27/2001 | James J. Barry | 12013/58401 | 8482 |

26646 7590 05/17/2005

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

STEWART, ALVIN J

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,833

Applicant(s)

BARRY ET AL.

Examiner

Alvin J Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The new changes made in the drawings filed in October 13, 2003 are accepted by the Examiner. New formal drawings are required if the case is allowed.

Response to Amendment

Applicant's arguments with respect to the 35 USC 103(a) rejections to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252.

Michal et al discloses a coated implant delivery system comprising an implant delivery device (10) with a first end (22), a second end (11), an inner lumen (see Fig. 8) and a stent (30). The first end has a releasable implant retention region (13), the region has an accessible surface (surface of the balloon), the accessible surface has a first implant adhesion-resistant coating (20) (see col. 7, lines 3-6; col. 7, lines 28-48) and the stent has a first implant coating (19) (see col. 10, lines 14-37). The two coatings are in physical communication with the stent and the accessible surface and the first implant coating face the releasable implant retention region.

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Stent (30) discloses a coating (18) made of two layers (19 & 20) (see Fig. 12 and col. 12, lines 23-27). The Examiner interpreted layer (20) of the stent (30) as being part of the retention region (13) because the layer (20) is in physical contact with the wall of the balloon (13). The Examiner interpreted layer (19) as being part of the stent because is in physical contact with the stent wall.

Regarding claims 6 and 7, see col. 1, lines 15-35).

Regarding claim 11, see col. 12, lines 14-17.

However, Michal does not disclose a stent having a first implant coating.

Hossainy et al teaches a stent having a plurality of coatings for the purpose of delivering therapeutic and pharmaceutical agents to a targeted area.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stent of the Michal et al reference to add a plurality of coatings around the stent in order to deliver therapeutic and pharmaceutical agents to a targeted area.

Claims 4, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252 and in further view of Sydney et al US Patent 6,306,144 B1.

Michal et al as modify by Hossainy et al disclose the invention substantially as claimed. Additionally, Michal et al discloses two coaxial sleeves positioned in physical communication with the retention region. The Examiner interpreted the two coating (19 & 20) as being the two coaxial sleeves. The two coatings run along the length of the stent, therefore, the two coatings are coaxial to the axis of the stent and have an open mesh sleeve configuration. However,

Michal et al as modify by Hossainy et al do not disclose an exterior of the second end of the implant delivery device treated with a second adhesion-resistant coating, a second adhesion-resistant coating on the accessible surface and a non-adhesive coating made of hydrogel.

Sydney et al teaches a stent delivery system having an implant delivery device (10), an elongated member (22), an inflatable member (18) and a stent (17). The elongated member (22) has a first end and a second end. The first end has a first coating and the second member has a second coating (see col. 2, lines 41-56 and col. 3, lines 16-19). The balloon comprises three different areas (32, 30 & 36) coated with two different lubricants (see col. 4, lines 52-62) for the purpose of avoiding unexpected movement of the stent when it is installed within the human body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the type of lubricants of the Michal et al reference with the different lubricants and the different coating location at the catheter of the Sydney et al reference in order to avoid unexpected movements of the stent during the installation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252 and in further view of Sahatjian et al US Patent 6,409,716 B1.

Michal et al as modify by Hossainy et al disclose the invention substantially as claimed. However, Michal et al as modify by Hossainy et al do not disclose a coating made of carbowax.

Sahatjian et al teaches a delivery system comprising an expandable balloon (4) and a stent (50). Additionally, Sahatjian discloses a coating soluble in water (e.g. carbowax) for the purpose of having a smooth delivery through the blood vessel (col. 3, lines 57-63).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the Michal et al reference with the carbowax coating of the Sahatjian et al in order to have a smooth delivery through the blood vessel (col. 3, lines 57-63).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal et al US Patent 6,287,285 B1 in view of Hossainy et al US Patent 6,153,252 and in further view of Brown US Patent 6,348,060 B1.

Michal et al as modify by Hossainy et al disclose the invention substantially as claimed. However, Michal et al as modify by Hossainy et al do not disclose a coating made of polymethacrylic (PEO).

Brown teaches a delivery system (10) comprising an expandable balloon (14) and a stent (18). Additionally, Brown discloses a coating made of PEO for the purpose of allowing a low profile on deflation of the balloon (see col. 4, lines 20-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coating of the Michal et al reference with the PEO coating of the Brown in order to allow a low profile on deflation of the balloon (see col. 4, lines 20-37).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit 3738

May 04, 2005.

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| Application Number  | Application No. | Applicant(s) | |
| | 09/842,833 | BARRY ET AL. | |
| | Examiner | Art Unit | |
| | Alvin J Stewart | 3738 | |